UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

COVENANT MEDICAL CENTER, INC.,

Plaintiff,

Case No. 07-15108

v.

Hon. John Corbett O'Meara

KATHLEEN SEBELIUS,
Secretary of Health and Human Services,

Defendant.
_____/

OPINION AND ORDER

Before the court are cross-motions for summary judgment on the administrative record, which have been extensively briefed. The court heard oral argument on June 4, 2009. For the reasons explained below, the court will grant Defendant's motion, deny Plaintiff's motion, and enter judgment in favor of Defendant.

PROCEDURAL BACKGROUND

Plaintiff, Covenant Medical Center, Inc., seeks reimbursement of certain medical education costs under Medicare. The Secretary of Health and Human Services determines the amount of Medicare Part A reimbursement to which participating hospitals are entitled. Various contractors, known as "fiscal intermediaries" (usually insurance companies) assist the Secretary in processing hospital claims. Hospitals are required to submit annual cost reports to their designated intermediary containing their claims for reimbursement. On the basis of the cost report, the intermediary makes as "final determination," also known as a "notice of program reimbursement," of the total amount the hospital should be reimbursed for the services it

rendered to Medicare beneficiaries during the reporting period. A hospital that wishes to challenge the amount of reimbursement it has received may request a hearing before the Provider Reimbursement Review Board ("PRRB"). The PRRB's decision is final, unless the Secretary, acting through the Centers for Medicare and Medicaid Services ("CMS") Administrator, chooses to review the decision within 60 days. A hospital may obtain judicial review of any "final decision" of the PRRB or the Secretary.

In this case, the intermediary denied reimbursement to Covenant for certain costs associated with the training of residents in non-hospital settings for the fiscal years 1999, 2000, and 2001. Covenant appealed to the PRRB. On August 2, 2007, the PRRB reversed the intermediary's decision. On October 3, 2007, the CMS Deputy Administrator reversed the PRRB's decision and upheld the intermediary's denial of reimbursement. The Deputy Administrator's decision is the final decision of the Secretary. Covenant seeks judicial review of the Secretary's decision denying reimbursement.

BACKGROUND FACTS

Covenant is a hospital based in Saginaw, Michigan. Covenant and St. Mary's Hospital own Synergy Medical Education Alliance, which is accredited to conduct medical education programs. Synergy operates clinics at which residents assigned to Covenant provide medical services to Medicare beneficiaries and other patients. Those residents are employed and compensated by Synergy. However, Covenant contends that it and St. Mary's funded Synergy for these training costs. Covenant states that it funded Synergy in proportion to the percentage of time that residents were assigned to the hospital. The residents rotated through Covenant, St. Mary's, the Synergy Clinic, and various physician's offices.

Prior to 1999, the intermediary reimbursed Covenant and St. Mary's through Medicare for training costs associated with the Synergy resident program. Covenant contends that since 75% of the residents who worked at the Synergy Clinic were assigned to the hospital, Covenant would claim, and the intermediary would allow, reimbursement for 75% of the offsite training costs incurred. (Covenant funded 75% of Synergy's operating costs; St. Mary's funded 25%.)

For fiscal years 1999, 2000, and 2001, however, the intermediary denied reimbursement in the amount of $2,596,238 for training costs associated with the Synergy offsite residents. The intermediary denied reimbursement because Covenant did not have a written agreement with Synergy Clinic or the other outside entities at which its residents were trained, as required by the Secretary's regulations. This decision was reversed by the PRRB, but reinstated by the Secretary.

LAW AND ANALYSIS

I. Standard of Review under the Administrative Procedure Act

When reviewing the final decision of an administrative agency, the court shall "hold unlawful and set aside the agency action" if the action is "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The court's review is limited to the evidence contained in the administrative record. See North Carolina Fisheries Ass'n v. Gutierrez, 518 F. Supp.2d 62, 79 (D.D.C. 2007). "Under the APA, it is the role of the agency to resolve factual issues to arrive at a decision that is supported by the administrative record, whereas 'the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.'" Id. (citation omitted). Summary judgment "serves as the mechanism for deciding, as a matter of

law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." Id.

"A court reviewing an agency's adjudicative action should accept the agency's factual findings if those findings are supported by substantial evidence on the record as a whole." Arkansas v. Oklahoma, 503 U.S. 91, 113 (1992). The agency's interpretation of the statute and regulations it administers is given deference, unless "arbitrary, capricious, or manifestly contrary to the statute." Chevron U.S.A., Inc. V. Natural Res. Def. Council, Inc., 467 U.S. 837, 844 (1984). See also National Ass'n of Home Builders v. Defenders of Wildlife, 551 U.S. 644, 658, 665 (2007); Kentucky Waterways Alliance v. Johnson, 540 F.3d 466, 473-475 (6th Cir. 2008).

II. Medicare Statute and Regulations

Hospitals may be reimbursed under Medicare for time spent by residents "in patient care activities" in a nonhospital setting "if the hospital incurs all, or substantially all, of the costs for the training program in that setting." 42 U.S.C. § 1395ww(d)(5)(B)(iv). The statute provides that the Secretary "shall establish rules . . . for the computation of the number of full-time-equivalent residents in an approved medical residency training program." 42 U.S.C. 1395ww(h)(4)(A). "Such rules shall provide that only time spent in activities relating to patient care shall be counted . . . without regard to the setting in which the activities are performed, if the hospital incurs all, or substantially all, of the costs for the training program in that setting." 42 U.S.C. 1395(h)(4)(E).

During the relevant period, the regulations required hospitals seeking Medicare reimbursement for the costs of training residents offsite to have a written agreement in place with each nonhospital site. See 42 C.F.R. §§ 412.105(f)(1)(ii)(C); 413.86(f)(4)(ii) (1999-2001).

The regulations provide that the time residents spend offsite may only be reimbursed if a "written agreement" is in place between the hospital and nonhospital site that (1) states that the hospital will incur the costs of the salaries and benefits of the residents while they are at the non-hospital site; (2) states that the hospital is providing reasonable compensation to the non-hospital site for supervisory training activities; and (3) indicates the compensation the hospital is providing. See 42 C.F.R. § 413.86(f)(4)(ii) (1999-2001); id. at § 412.105(f)(1)(ii)(C). The hospital also "must incur all, or substantially all, of the costs" of the residents' training. 42 C.F.R. § 413.86(f)(4)(iii). See also 63 Fed. Reg. 40954, 40986-40996 (July 31, 1998) (proposing written agreement rule to go in effect January 1, 1999).

The written agreement regulation was rescinded 2004. The Secretary explained:

> We required the written agreements in regulations in order to provide an administrative tool for use by the fiscal intermediaries to assist in determining whether hospitals would incur all or substantially all of the costs of the training in the nonhospital setting. . . . [However,] the fiscal intermediaries have encountered numerous situations where hospitals have complied with the requirement to incur all or substantially all of the costs of training in nonhospital settings. However, despite our longstanding regulations that state the requirement for a written agreement, these hospitals have not met the regulatory requirements related to written agreements. . . . In retrospect, we believe the regulatory requirements concerning the written agreements may not have been the most efficient aid to fiscal intermediaries in determining whether hospitals would actually incur all or substantially all of the costs of the training programs in nonhospital settings.

69 Fed. Reg. 49179 (Aug. 11, 2004).

III. Covenant's Challenges to the Denial of Reimbursement

Covenant challenges the denial of reimbursement for training costs on three grounds: (1) the written agreement regulation is invalid as a matter of law; (2) the regulation does not apply to

"related parties," and (3) in any event, Covenant has substantially satisfied the written agreement regulation.

A. Validity of the Written Agreement Regulation

Covenant argues that the written agreement regulation is invalid because it conflicts with the language of the Medicare Act. Covenant contends that the Act only has two requirements for reimbursement of medical education costs: (1) the costs are for "patient care"; and (2) the hospital has incurred "all, or substantially all, of the costs for the training program." According to Covenant, the written agreement regulation adds a third requirement that is inconsistent with the statute.

When reviewing an agency's interpretation of the statute it administers, the court engages in two-step analysis:

> "First, always, is the question whether Congress has directly spoken to the *precise* question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." The Supreme Court has explained that "[t]he judiciary is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear legislative intent" Chevron, 467 U.S. at 843 n.9, 104 S.Ct. 2778.
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> Second, if we determine that Congress has not directly addressed the precise question at issue, that is, that the statute is silent or ambiguous on the specific issue, we must determine "whether the agency's answer is based on a permissible construction of the statute." [T]he agency's construction is entitled to deference unless "arbitrary, capricious, or manifestly contrary to the statute." Chevron, 467 U.S. at 844, 104 S.Ct. 2778.

Clark Reg'l Med. Ctr. v. U.S. Dept. of Health & Human Serv., 314 F.3d 241, 244-45 (6th Cir. 2002) (some citations omitted). The statute itself is silent with respect to whether a written

agreement is required to demonstrate that a hospital has incurred all or substantially all of the costs of a medical training program. Accordingly, the court must decide whether the written agreement regulation is "arbitrary, capricious, or manifestly contrary to the statute." Id.

The regulation, which is intended to ensure that a hospital has actually incurred all or substantially all of the costs it seeks, is not arbitrary, capricious, or manifestly contrary to the Medicare Act. The written agreement requirement ensures that both the hospital and non-hospital setting are not paid for the same cost. Moreover, the Medicare Act specifically bars the Secretary from making payments "to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider. . . ." 42 U.S.C. § 1395g(a). See Chestnut Hill Hosp. v. Thompson, 2006 WL 2380660 (D. D.C. Aug. 15, 2006) (finding that the Secretary had the authority to impose written agreement requirement); Cottage Health Sys. v. Sebelius, __ F. Supp.2d __, 2009 WL 1919303 (D.D.C. July 7, 2009) (same; following Chestnut Hill). The written agreement regulation is a reasonable way in which the Secretary may verify, as it is statutorily required to do, that a hospital is actually incurring the costs for which it seeks reimbursement. Covenant's argument that the written agreement regulation constitutes an impermissible "third requirement" contrary to the Medicare Act "would prove too much, foreclosing here the application of any of a host of requirements imposed by the Secretary to ensure the orderly administration of the Medicare program." Chestnut Hill, 2006 WL 2380660 at *4.

Further, the fact that the regulation was ultimately rescinded, in itself, has no bearing on its validity while it was in effect. See National Cable & Telcomms. Ass'n v. Brand X Internet Servs., 545 U.S. 967, 981-82 (2005) ("Agency inconsistency is not a basis for declining to

analyze the agency's interpretation under the Chevron framework. . . . For if the agency adequately explains the reasons for a reversal of policy, 'change is not invalidating, since the whole point of Chevron is to leave the discretion provided by the ambiguities of a statute with the implementing agency.'"). See also FCC v. Fox Television Stations, Inc.,129 S. Ct. 1800, 1810-11 (2009) ("We find no basis in the Administrative Procedure Act or in our opinions for a requirement that all agency change be subjected to more searching review.").

B. The Written Agreement Regulation Applies to "Related Parties"

Covenant argues that because it and Synergy are "related parties" under the Medicare regulations, the written agreement regulation does not apply. A provider is related to another organization if "the provider to a significant extent is associated or affiliated with or has control of or is controlled" by another organization. See 42 C.F.R. § 413.17(b)(1). The related party regulation is designed to avoid payment of artificially inflated costs that might be generated by less than arms-length bargaining, and thereby to prevent inflated costs from being borne by the Medicare program. The regulation states:

> If the provider obtains items of services, facilities, or supplies from an organization, even though it is a separate legal entity, and the organization is owned or controlled by the owner(s) of the provider, in effect the items are obtained from itself. An example would be a corporation building a hospital or a nursing home and then leasing it to another corporation controlled by the owner. Therefore, reimbursable cost should include the costs for these items at the cost to the supplying organization. However, if the price in the open market for comparable services, facilities, or supplies is lower than the cost to the supplier, the allowable cost to the provider may not exceed the market price.

42 C.F.R. 413.17(c)(2).

Covenant takes this regulation to mean that, for the purposes of the Medicare Act, it and

Synergy are the same entity. Accordingly, Covenant argues, the written agreement regulation should not apply, because Covenant should not have to enter into an agreement with itself. Further, Covenant notes, Synergy did have written agreements with non-hospital settings, so Covenant should also be found to have these agreements, since it is allegedly the same entity as Synergy.

Contrary to Covenant's argument, the written agreement regulation and the related party regulation are not inconsistent. The related party regulation prevents companies controlled by a provider from making an inflated profit at Medicare's expense. The written agreement regulation is an attempt to ensure that a provider is actually incurring the training costs for which it seeks reimbursement. Simply because Covenant and Synergy are "related parties" does not assure the Secretary that the hospital is financially responsible for paying "all or substantially all" of the training costs at the non-hospital settings. The Secretary's interpretation of the written agreement regulation as applying to related parties is reasonable.

This is particularly true given that the court's review of an agency's interpretation of its own regulations is "highly deferential." See Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 512 (1994); Battle Creek Health Sys. v. Leavitt, 498 F.3d 401, 408-409 (6th Cir. 2007). The court's task is "not to decide which among several competing interpretations best serves the regulatory purpose." Thomas Jefferson Univ., 512 U.S. at 512. Rather, an agency's interpretation of a regulation "must be given 'controlling weight unless it is plainly erroneous or inconsistent with the regulation.'" Id. This deference is particularly proper when a rule concerns a complex and highly technical regulatory program, like Medicare. Id.

C. Covenant Has Not Complied with the Written Agreement Requirement

Covenant also argues that it has substantially complied with the written agreement requirement because it has submitted various documents demonstrating that it did incur the costs requested. Covenant submitted hundreds of pages of documents that it argues collectively satisfy the written agreement requirement. None of these documents, however, demonstrate that Covenant incurred all or substantially all of the costs associated with training residents – such as resident salaries and benefits.[1]

The purpose of requiring an "agreement" as opposed to a collection of documents is so the intermediary and Secretary do not have to comb through hundreds of pages to find out whether a hospital incurred all or substantially all of the costs of a training program. The Secretary's determination that Covenant's collection of documents does not comply with the written agreement requirement is reasonable and supported by substantial evidence. See Cottage Health, 2009 WL 1919303 at *10-11; Chestnut Hill, 2006 WL 2380660 at *5.

IV. Conclusion

In light of the deferential standard of review, the court will affirm the decision of the Secretary.

[1] Indeed, these costs were paid by Synergy. Covenant funds 75% of Synergy. There is no documentation, however, indicating how much of the training costs are borne by Covenant.

ORDER

IT IS HEREBY ORDERED that Defendant's motion for summary judgment is GRANTED.

IT IS FURTHER ORDERED that Plaintiff's motion for summary judgment is DENIED.

s/John Corbett O'Meara
United States District Judge

Date: September 10, 2009

I hereby certify that a copy of the foregoing document was served upon the parties of record on this date, September 10, 2009, by electronic and/or ordinary mail.

s/William Barkholz
Case Manager